JUN 14 2011

5. 510(k) SUMMARY

March 25, 2010

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Nanette Hedden
Senior Manager, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL, 60085
Telephone: (847) 270-4871
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DEVICE NAME:

Trade name: Additive Cap

Common name: Additive Cap

Classification name: Container I.V., 21 CFR 880.5025, KPE, Class II

PREDICATE DEVICE:

Table 5-1.
Previous 510(k)s

Device	Company	Previous 510(k)	Clearance date
Additive Cap	Baxter Healthcare	K760880	December 30, 1976

DESCRIPTION OF THE DEVICE:

The subject of this submission is an Additive Cap which will be indicated for use on the medication port of VIAFLEX and AVIVA containers to provide visual evidence that medication has been added. The material and design of the cap are not changing. The proposed Additive Cap will continue to be non-fluid path and non-sterile. The only change is a label modification to expand the indications for use statement to identify compatibility with an additional I.V. container (AVIVA). The device is marketed as a stand-alone device and is packaged in bulk.

STATEMENT OF INTENDED USE:

Additive Cap is indicated for use on the medication port of VIAFLEX and AVIVA containers to provide visual evidence that medication has been added.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The Additive Cap is an injection molded, polypropylene component. The intended use and function of the proposed Additive Cap is identical to the predicate device. The material and design of the cap are not changing. The proposed Additive Cap will continue to be non-fluid path and non-sterile. The only change is a label modification to expand the indications for use statement by adding compatibility with the AVIVA container.

Performance Data: A protocol was conducted to evaluate the force to remove the Additive Cap from the medication port when used with AVIVA and VIAFLEX containers.

Biocompatibility: The subject device does not contact the patient's body directly or indirectly. Baxter assessed the biocompatibility testing requirements for the device based on FDA Blue Book Memorandum G-95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and internal Baxter procedures. Based on this assessment, a biocompatibility assay for the Additive Cap was performed per test method described in Biological Evaluation of Medical Devices ISO 10993-5: Tests for cytotoxicity: *in vitro* methods. The polypropylene material used to mold the Additive Cap was determined to be biocompatible and appropriate for its intended use.

DISCUSSION OF NONCLINICAL TESTS:

All test results meet the acceptance criteria and support that the device is appropriately designed for the intended use.

CONCLUSION:

The Additive Cap is substantially equivalent to Baxter's current legally marketed Additive Cap, cleared December 30, 1976 (K760880).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Nanette Hedden
Senior Manager
Baxter Healthcare Corporation
Medical Products
1620 Waukegan Road
McGaw Park, Illinois 60085

JUN 14 2011

Re: K111217
Trade/Device Name: Additive Cap
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: II
Product Code: KPE
Dated: June 6, 2011
Received: June 8, 2011

Dear Ms. Hedden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K111217

Device Name: Additive Cap

Indications for Use:

Additive Cap is indicated for use on the medication port of VIAFLEX and AVIVA containers to provide visual evidence that medication has been added.

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Acting for Richard Chapman

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111217
